ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Total Annual Burden Hours: 13,746				

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarify of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 8, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–18658 Filed 7–13–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Relocation of the Dockets Management Branch; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 16, 1998 (63 FR 32888). The document announced the relocation and partial closing of the Dockets Management Branch (DMB). The document published with an incorrect zip code. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennie C. Butler, Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–6860.

In FR Doc. 98–15878, appearing on page 32888, in the **Federal Register** of Tuesday, June 16, 1998, the following corrections are made:

1. On page 32888, in the second column, under ''**SUPPLEMENTARY INFORMATION**,'' in line six, the zip code is corrected to read ''20852,'' and in the second paragraph, in line eleven, the zip code is corrected to read ''20852.''

Dated: July 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18691 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0481]

Guidance for Industry on 180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' The purpose of the guidance is to inform the public of FDA's application of the 180-day generic drug exclusivity provisions of the Federal Food, Drug, and Cosmetic Act (the act) in light of recent court decisions on the issue.

DATES: Written comments may be submitted on the guidance document by October 13, 1998. General comments on the agency guidances are welcome at any time.

ADDRESSES: Copies of the guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance to the Dockets Management Branch, (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), 7500 Standish Pl., Rockville, MD 20855, 301–827–5846.

SUPPLEMENTARY INFORMATION: A requirement of FDA's regulations implementing the 180-day generic drug exclusivity provisions of the act has recently been successfully challenged in court. Section 314.107(c)(1) (21 CFR 314.107(c)(1)) applies and interprets section 505(j)(5)(B)(iv) of the act (21 U.S.C. 355(j)(5)(B)(iv)). Section 314.107(c)(1) contains the ''successful defense'' provision, which requires an abbreviated new drug application (ANDA) applicant to be sued for patent infringement and to prevail in the litigation in order to receive the 180-day period of marketing exclusivity. Two recent circuit court decisions, *Mova Pharmaceutical Corp.* v. *Shalala*, No. 97–5082, 1998 U.S. App. Lexis 7391 (D.C. Cir. Apr. 14, 1998) and *Granutec, Inc.* v. *Shalala*, No. 97–1873 and No. 97–1874, 1998 U.S. App. LEXIS 6685, (4th Cir. Apr. 3, 1998), held that the ''successful defense'' requirement was not supported by the act. The effect of these decisions, together with a June 1, 1998, order of the district court in *Mova*, is that FDA will not enforce the ''successful defense'' provisions of § 314.107(c)(1).

FDA intends to formally remove the ''successful defense'' provisions from § 314.107(c)(1), but that process is not complete. Following withdrawal of the regulatory provision, FDA expects to begin a rulemaking to issue new